

## **REMARKS**

Claims 1-5 are pending in the application with claim 2 being withdrawn, claims 1 and 3-4 being amended herein and new claim 5 is added. The newly added feature to claims 1 and 3-4 is added to further specify the process of extracting *Radix Stephaniae tetrandrae*. Support for this amendment may be found in Example 1. Claim 5 is added to further specify the components of the SPRST extract by referring to the HPLC fingerprint. The result of the HPLC fingerprint is included in the specification and shown in Fig. 1b. Thus, the amendments and new claim 6 do not include new matter.

In addition, the specification has been amended to correct readily apparent typographical errors in some of the symbols.

### **Communication of September 26, 2006**

On August 21, 2006 Applicants filed a supplemental response to the Office Action of February 3, 2006, prior to the issuance of the present final office action on August 25, 2006. The Examiner indicated in the paper issued September 26, 2006, that the supplement response was not considered as provided under MPEP§714.03(a). However, it is within the Examiner's discretion to have considered such a reply.

In addition, MPEP §714.03 further provides that "If applicant wishes to have a not-entered supplemental reply considered, applicant should include the changes in a reply filed in response to the next Office action.". The changes to the specification and new claim 5 (presented as new claim 6 in the supplemental response) were part of the supplemental reply filed on August 21, 2006. In addition, the amended subject matter added to claims 1 and 3-4 is subject matter presented for consideration in the supplemental response as new claim 5 (in the supplemental response). As such, entry and consideration thereof as part of the present response are respectfully requested, as provided for under MPEP§714.03.

**Rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

Claims 1, 3 and 4 have been rejected under 35 U.S.C. §112. Claims 1, 3 and 4 have been amended to define specially processed extract as being “prepared by extracting *Radix Stephaniae tetrandrae* with 95% ethanol at 60°C three times.” Withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §102**

Claims 1, 3 and 4 remain rejected under 35 U.S.C. §102(b) as being anticipated by Chou et al. In addition, claims 1, 3 and 4 remain rejected under 35 U.S.C. §102(b) as being anticipated by USP 6,218,514.

Chou et al. is asserted to teach an extract from *Stephaniae tetrandrae* roots that contains tetradiine, fangchinoline, cyclanoline and oblongine, which can be used to modulate cardiovascular disease and inflammation. Applicants traverse this rejection and withdrawal thereof is respectfully requested. US '541 is asserted to teach an extract from *Stephaniae tetrandrae* roots that contains tetradiine, fangchinoline and cyclanoline. The Examiner notes that the reference does not disclose the presence of oblongine in the extract. However, the Examiner asserts that the reference extraction method and that disclosed in the instant specification are similar enough that oblongine would also be present in the reference extract. Finally, the Examiner notes that since the alkaloids are present in *Stephaniae tetrandrae* roots they would inherently be present in any extract made from the roots. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The instant invention, as recited in claims 1, is drawn to a specially processed extract of *Radix Stephaniae tetrandrae* (SPRST) comprising tetrandrine (Tet), fangchinoline (Fan), cyclanoline (Cyc) oblongine (Obl) alkaloids and other compounds with biological activity. The

Examiner points to the disclosure in the references of extracts containing the four recited alkaloids. However, the Examiner has failed to consider the recited feature of the claims that the extract of the invention also contains other compounds with biological activity.

As noted previously, the present inventors have found that their extract ("SPRST") contains components that present additional to the alkaloids. This can be seen from the HPLC data of the specification. With the extract of the invention, Tet and Fan need only be present at concentrations of approximately 1.3% and 0.7%, respectively, but the potency of the extract is the same as pure Tet. However, when the same concentrations of Tet and Fan are used in the absence of the additional compounds that are present in the extract there is no anti-inflammatory effect. In addition, because of the reduced concentrations of Tet and Fan that are needed with the instant extract, the toxicity of the SPRST is much lower than when Tet and/or Fan are used in the absence of other compounds. The presence of these additional compounds is dependent on the specific preparation method used to make the extract of the invention. In this regard, claims 1 and 3-4 have been amended to define that specific process that is needed to obtain the extract of the invention having the additional active components. In addition, new claim 5 was added to further specify the components of the SPRST extract by referring to the HPLC fingerprint.

While the inventors have not identified the other compounds present in the SPRST, they have shown that these compounds are consistently present in the extract when prepared in accordance with the process now recited in claims 1 and 3-4. The SPRST extract of the invention contains the additional components that are not disclosed in Chou et al. These additional compounds result in properties of the extract that are not seen in the prior art extracts, i.e. lower toxicity and increased anti-inflammatory activity by the Tet and Fan that are present. As such, the invention is not anticipated by the reference and withdrawal of the rejection is respectfully requested.

The discussion above regarding the distinctions between the extract of Chou et al. and the SPRST extract of the instant invention are equally applicable to US '541. US '541 similarly fails to disclose or suggest the additional compounds that are present with the claimed SPRST extract, when made according to the process as recited in claims 1 and 3-4. As such, US '541 does not anticipate the invention and withdrawal of the rejection is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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